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(54) Title: A SUPPORT FRAME FOR AN EMBOLIC PROTECTION DEVICE
(54) Titre: TRAME DE SUPPORT POUR DISPOSITIF DE PROTECTION CONTRE LES EMBOLIES

(57) Abstract

An embolic protection device (100) comprises a collapsible filter element (105) for delivery through a vascular system of a patient. The filter element (105) comprising a collapsible filter body (110) and a filter support frame (111) contacting the filter body (110). The collapsible filter body (110) has an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings (117) sized to allow blood and embolic material enter the filter body (110), the outlet end of the filter body having a plurality of outlet openings (119) sized to allow through passage of blood but to retain undesired embolic material within the filter body (110). The filter support frame (111) is movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body (110) in the expanded position. The frame (111) has a plurality of engagement segments which are spaced-apart longitudinally and transversely when the filter body (110) is in the deployed expanded configuration to urge the filter body (110) into opposition with the vessel wall. The engagement segments define at least partially a substantially helical engagement track.

(57) Abrégé

L'invention concerne un dispositif de protection (100) contre les embolies, comprenant un élément de filtre (105) repliable à introduire dans le système vasculaire d'un patient. Cet élément de filtre (105) comprend un corps de filtre (110) repliable, et une trame de support (111) de filtre en contact avec ledit corps de filtre (110). Ce corps de filtre (110) repliable comprend une extrémité d'entrée et une extrémité de sortie, l'extrémité d'entrée présentant une ou plusieurs ouvertures d'entrée (117) dimensionnée(s) de façon à permettre au sang et au matériau embolique d'entrer dans ledit corps de filtre (110), l'extrémité de sortie présentant une pluralité d'ouvertures de sortie (119) dimensionnées de façon à permettre le passage du sang, et à retenir le matériau embolique non désiré dans le corps de filtre (110). La trame de support (111) de filtre est mobile entre une position repliée permettant son déplacement dans le système vasculaire, et une position étendue faisant saillie vers l'extérieur de façon à supporter le corps de filtre (110) dans une position déployée. La trame (111) possède une pluralité de segments d'accouplement espacés longitudinalement et transversalement lorsque le corps de filtre (110) se trouve dans une configuration étendue déployée, de façon à pousser ledit corps de filtre (110) dans une position adjacente à la paroi de vaisseau. Ces segments d'accouplement définissent au moins partiellement une voie d'accouplement sensiblement hélicoïdale.

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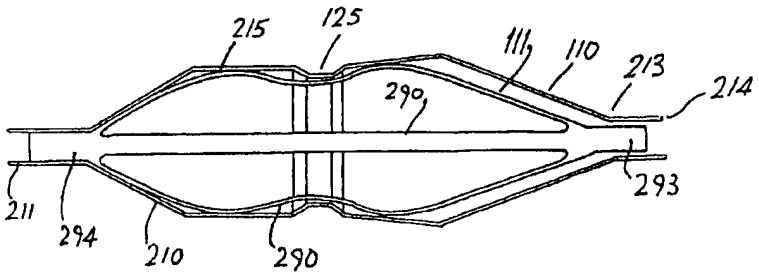

(57) Abstract

An embolic protection device (100) comprises a collapsible filter element (105) for delivery through a vascular system of a patient. The filter element (105) comprising a collapsible filter body (110) and a filter support frame (111) contacting the filter body (110). The collapsible filter body (110) has an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings (117) sized to allow blood and embolic material enter the filter body (110), the outlet end of the filter body having a plurality of outlet openings (119) sized to allow through passage of blood but to retain undesired embolic material within the filter body (110). The filter support frame (111) is movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body (110) in the expanded position. The frame (111) has a plurality of engagement segments which are spaced–apart longitudinally and transversely when the filter body (110) is in the deployed expanded configuration to urge the filter body (110) into opposition with the vessel wall. The engagement segments define at least partially a substantially helical engagement track.

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Description

"A Support Frame for an Embolic Protection Device"

This invention relates to a filter element for a transcatheter embolic protection device.

Introduction

The invention is particularly concerned with filter elements for transcatheter embolic protection devices of the type described in our WO-A-9923976. One type of such embolic filter essentially comprises a filter body mounted on an associated collapsible support frame which can be collapsed by means of a catheter for deployment of the filter through a patient's vascular system. Upon retraction of the catheter the support frame and filter body expand outwardly from across a blood vessel within which the filter is positioned to filter blood flowing through the blood vessel.

The support structure is generally of superelastic or shaped memory material such as nitinol which provides the circumferential pressure on expansion to secure the filter body in a close fit within the vessel.

It is important to achieve apposition of a filter body with the wall of the vessel in which the filter is deployed to ensure that there is no pathway between the filter body and the vessel wall through which embolic material could pass. This is not a simple issue in view of the wide variations in vessel geometry and the variable physical properties of a vessel lining at different locations even within a single vasculature.

When the filter element is being pulled through a small diameter conduit or opening for loading and retrieval, there are certain forces exerted on the support frame. The first is on entry of the proximal end into the tube and when the whole

of the proximal end has been inserted into the tube and the distal end is about to be inserted into the catheter tube. Considerable loading forces are generated which in some cases require considerable retraction forces to overcome.

There is therefore a need to provide a support frame for a filter which will address these problems.

Statements of Invention

According to the invention there is provided an embolic protection device comprising:

a collapsible filter element for delivery through a vascular system of a patient;

the filter element comprising a collapsible filter body and a filter support frame contacting the filter body;

the collapsible filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

the filter support frame having a longitudinal axis and being movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body in the expanded position;

the frame having a plurality of engagement segments, the engagement segments being spaced-apart longitudinally and transversely when the filter

is in the deployed expanded configuration to urge the filter body into apposition with the vessel wall.

In one embodiment of the invention the engagement segments define at least one at least partially substantially helical engagement track.

Preferably the frame comprises a number of frame elements, at least some of the frame elements having an engagement segment. Ideally at least some of the frame elements are interconnected.

In another embodiment of the invention the frame has an intermediate section and a proximal section extending from the intermediate section, the engagement segments being provided in the intermediate section of the frame. Preferably the proximal section of the frame extends radially inwardly of the intermediate section and defines at least one inlet hole to accommodate inflow of embolic material to be captured in the filter. Most preferably the proximal section of the frame has a proximal mounting for mounting on a filter carrier. Ideally the proximal mounting is substantially tubular.

The proximal mounting may be offset with respect to the longitudinal axis of the support frame.

In a particularly preferred embodiment the proximal section of the frame is flexible with respect to the intermediate section of the frame. Ideally the proximal section of the frame comprises a number of proximal elements, at least some of which are of a flexible material. Most preferably the proximal section of the frame comprises a plurality of flexible elements of relatively low column strength which are movable individually and independently of the intermediate section between taut and slack configuration.

In a further embodiment of the invention the frame includes a distal section extending from the intermediate section, the distal section of the frame being flexible with respect to the intermediate section of the frame. Preferably the distal section of the frame includes a plurality of flexible elements of relatively low column strength which are movable individually and independently of the intermediate section between taut and slack configurations. Ideally the flexible elements are thread-like elements. Most preferably at least some of the flexible elements define tethers.

In another preferred embodiment of the invention the frame has a distal section extending from the intermediate section. Preferably the distal section of the frame extends radially inwardly of the intermediate section. Ideally the distal section of the frame has a distal mounting for mounting on a filter carrier.

The distal mounting is preferably substantially tubular.

In one embodiment of the invention the distal mounting is offset with respect to the longitudinal axis of the support frame.

Preferably the distal section of the frame is flexible with respect to the intermediate section of the frame.

At least the intermediate section of the support frame may be formed from wire.

Alternatively at least the intermediate section of the support frame may be formed by a slotted tube.

In a preferred embodiment at least the intermediate section of the support frame is an elastic, superelastic and/or a shaped memory material. Ideally at least the intermediate section of the support frame is of Nitinol.

Desirably the included angle defined between adjacent frame elements is less than 90°. Most preferably the included angle is less than 60°.

In a further preferred embodiment at least a portion of a support frame element is offset from the longitudinal axis by an angle of less than 45° in the expanded configuration.

Desirably a support frame element is offset from the longitudinal axis by an angle of less than 10° when the frame is in the collapsed configuration. Most preferably a support frame element is offset from off the longitudinal axis by angles of less than 5° when the frame is in the collapsed configuration.

Ideally the engagement segments are defined by segments of a single frame element. The frame element is preferably at least partially of helical shape.

Desirably the collapsible filter body is mounted to the support frame.

In another aspect the invention provides an embolic protection device comprising:

a collapsible filter element for delivery through a vascular system of a patient;

the filter element comprising a collapsible filter body and a filter support frame contacting the filter body;

the collapsible filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

the filter support frame having a longitudinal axis and being movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body in the expanded position;

the frame having an intermediate section and a proximal section extending from the intermediate section; and

the proximal section of the frame being flexible with respect to the intermediate section of the frame.

In one embodiment of the invention the proximal section of the frame comprises a plurality of flexible elements of relatively low column strength which are movable individually and independently of the intermediate section between taut and slack configuration.

In a preferred embodiment the frame includes a distal section extending from the intermediate section, the distal section of the frame being flexible with respect to the intermediate section of the frame. Preferably the distal section of the frame includes a plurality of flexible elements of relatively low column strength which are movable individually and independently of the intermediate section between taut and slack configurations. Ideally the flexible elements are thread-like elements.

Most preferably at least some of the flexible elements define tethers.

Brief Description of the Drawings

The invention will be more clearly understood by the following description of some of the embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which: -

Fig. 1 is partially sectioned elevational view an embolic protection device;

Fig. 2 is a schematic sectional elevational view of the embolic protection device of Fig. 1;

Fig. 3 is a detail sectional view of portion of the device of Fig. 1;

Fig. 4 is a longitudinal cross sectional view of the device of Fig. 1;

Fig. 5 is a cross sectional view of a distal end of the device of Fig. 1;

Fig. 6 is a view on the line A-A in Fig. 5;

Fig. 7 is a perspective view of a filter body of the device of Figs. 1 to 6;

Fig. 8 is a side elevational view of the filter body of Fig. 7;

Fig. 9 is a view on a proximal end of the filter body;

Fig. 10 is a perspective view of a support frame of the device of Figs. 1 to 6;

Fig. 11 is a side elevational view of the support frame;

Fig. 12 is a perspective view illustrating the manufacture of the support frame;

Fig. 13 is a view of the support frame and filter element assembly;

Fig. 14 is a longitudinal cross sectional view of a filter element according to the invention;

Fig. 15 is a longitudinal cross sectional view a support frame of the filter element of Fig. 14;

Fig. 16 is a cross sectional on the line III-III of Fig. 15;

Fig. 17 is a cross sectional view on the line IV-IV of Fig. 15;

Fig. 18 is a cross sectional view on the line V-V of Fig. 15;

Fig. 19 is a longitudinal cross section view of another support frame;

Fig. 20 is a side elevational view of a filter support frame according to another embodiment of the invention;

Fig. 21 is a side elevational view of another support frame of the invention;

Fig. 21a is a side view of one support element of the frame of Fig. 21;

Fig. 22 is a perspective view of another support frame;

Fig. 23 is a longitudinal cross sectional view of a further support frame, in a deployed use configuration;

Fig. 24 is a side view of another support frame in a partially collapsed configuration;

Fig. 25 is a longitudinal cross sectional view of the support frame of Fig. 24 in a deployed use configuration;

Fig. 26 is a side view of another support frame;

Fig. 27 is a side view of a still further support frame and filter of the invention;

Fig. 28 is a perspective view of another support frame;

Fig. 29 is a perspective view of yet another support frame;

Figs. 30 and 31 are side views of another support frame in different positions of use;

Figs. 32 and 33 are perspective views of a support frame in different positions of use;

Fig. 34 is a perspective view of a further support frame of the invention; and

Fig. 35 is a perspective view of the support frame of Fig. 34 and an associated filter.

Detailed Description

Referring to Figs. 1 to 13 there is illustrated an embolic protection device as described in our WO-A-9923976 indicated generally by the reference number 100. The device 100 has a guidewire 101 with a proximal end 102 and a distal end 103.

A tubular sleeve 104 is slidably mounted on the guidewire 101. A collapsible filter 105 is mounted on the sleeve 104, the filter 105 being movable between a collapsed stored position against the sleeve 104 and an expanded position as shown in the drawings extended outwardly of the sleeve 104 for deployment in a blood vessel.

The sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101.

The filter 105 comprises a filter body 110 mounted over a collapsible support frame 111. The filter body 110 is mounted to the sleeve 104 at each end, the body 110 being rigidly attached to a proximal end 112 of the sleeve 104 and the body 110 being attached to a collar 115 which is slidable along a distal end 114 of the sleeve 104. Thus the distal end of the body 110 is longitudinally slidable along the sleeve 104. The support frame 111 is also fixed at the proximal end 112 of the sleeve 104. A distal end 116 of the support frame 111 is not attached to the sleeve 104 and is thus also free to move longitudinally along the sleeve 104 to facilitate collapsing the support frame 111 against the sleeve 104. The support frame 111 is such that it is naturally expanded as shown in the drawings and can be collapsed inwardly against the sleeve 104 for loading in a catheter 118 or the like.

The filter body 105 has large proximal inlet openings 117 and small distal outlet openings 119. The proximal inlet openings 117 allow blood and embolic material to enter the filter body, however, the distal outlet openings 119 allow through passage of blood but retain undesired embolic material within the filter body.

An olive guide 120 is mounted at a distal end of the sleeve 104 and has a cylindrical central portion 121 with tapered ends 122, 123. The distal end 122 may be an arrowhead configuration for smooth transition between the catheter and olive surfaces. The support frame 111 is shaped to provide a circumferential

groove 125 in the filter body 110. If the filter is too large for a vessel, the body may crease and this groove 125 ensures any crease does not propagate along the filter.

Enlarged openings are provided at a proximal end of the filter body 110 to allow ingress of blood and embolic material into an interior of the body 110.

In use, the filter 105 is mounted in a collapsed state within a distal end of the catheter 118 and delivered to a deployment site. When the filter is correctly positioned the catheter 118 is retracted allowing the support frame 111 to expand expanding the filter body 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the filter body 110. The blood will pass through the filter wall, however, the openings or pores in the filter are sized so as to retain the embolic material. After use the catheter is delivered along the guidewire 101 and slid over the filter 105 engaging the proximal inlet end 112 first to close the openings and then gradually collapsing the filter body against the sleeve 104 as the catheter 118 advances over the filter 105. Once the filter 105 is fully loaded in the catheter 118, it can then be withdrawn.

It will be noted that a proximal end of the filter is fixed and a distal end of the filter is longitudinally movable along the sleeve to facilitate collapsing of the filter body.

Further, the catheter engages the proximal end of the filter body first thus closing the filter body inlet and preventing escape of embolic material from the filter body as the filter body is being collapsed.

The outer filter body 110 is preferably of a resilient biocompatible elastomeric material. The material may be a polyurethane based material. There are a series of commercially available polyurethane materials that may be suitable. These are

typically based on polyether or polycarbonate or silicone macroglycols together with diisocyanate and a diol or diamine or alkanolamine or water chain extender. Examples of these are described in EP-A-461,375 and US 5,621, 065. In addition, polyurethane elastomers manufactured from polycarbonate polyols as described in US 5,254,622 (Szycher) are also suitable.

The filter material may also be a biostable polycarbonate urethane article an example of which may be prepared by reaction of an isocyanate, a chain extender and a polycarbonate copolymer polyol of alkyl carbonates. This material is described in our WO-A-9924084. The filter material may be manufactured from a block and cut into a desired shape. However the filter is preferably formed by dipping a rod of desired geometry into a solution of the material which coats the rod. The rod is then dissolved. The final geometry of the filter may be determined in the dipping step or the final geometry may be achieved in a finishing operation. Typically the finishing operations involve processes such as mechanical machining operations, laser machining or chemical machining.

The filter body is of hollow construction and is formed as described above by dipping a rod in a solution of polymeric material to coat the rod. The rod is then dissolved, leaving a hollow body polymeric material. The rod may be of an acrylic material which is dissolved by a suitable solvent such as acetone.

The polymeric body thus formed is machined to the shape illustrated in Figs. 1 to 13. The final machined filter body comprises an inlet or proximal portion 210 with a proximal neck 212, and outlet or distal portion 213 with a distal neck 214, and an intermediate portion 215 between the proximal and distal portions.

The inlet holes 117 are provided in the proximal portion 210 which allow the blood and embolic material to flow into the filter body. In this case the proximal portion 210 is of generally conical shape to maximise the hole size.

The intermediate portion 215 is also hollow and in this case is of generally cylindrical construction. This is important in ensuring more than simple point contact with the surrounding blood vessel. The cylindrical structure allows the filter body to come into soft contact with the blood vessel to avoid damaging the vessel wall.

The intermediate portion 215 is provided with a radial stiffening means, in this case in the form of a radial strengthening ring or rim 220. The ring 220 provides localised stiffening of the filter body without stiffening the material in contact with the vessel. Such an arrangement provides appropriate structural strength so that line apposition of the filter body to the vessel wall is achieved. It is expected that other geometrics of stiffening means will achieve a similar result.

The tubular intermediate portion 215 is also important in maintaining the stability of the filter body in situ to retain captured emboli and to ensure that flow around the filter is minimised. For optimum stability we have found that the ratio of the axial length of the intermediate portion 215 of the filter body to the diameter of the intermediate portion 215 is preferably at least 0.5 and ideally greater than 1.0.

The collapsible support frame 111 has four foldable arms 290 which are collapsed for deployment and upon release extend outwardly to expand the filter body 110.

The support frame 111 can be manufactured from a range of metallic or polymeric components such as a superelastic or shape memory alloy like nitinol or a shape memory polymer or a shaped stainless steel or metal with similar properties that will recover from the deformation sufficiently to cause the filter body 110 to open.

The support frame may be formed as illustrated in Fig. 12 by machining slots in a tube 291 of superelastic material or shape memory alloy such as nitinol. On machining, the unslotted distal end of the tube forms a distal collar 293 and the unslotted proximal end of the tube forms a proximal collar 294. In use, the distal

collar 293 is slidably moveable along the tubular sleeve 104 which in turn is slidably mounted on the guidewire 101 for deployment and retrieval. The proximal collar 294 is fixed relative to the tubular sleeve 104.

Alternatively, the construction may be made entirely of wires interconnected at various points.

To load the filter, the sub assembly of the support frame and filter body is pulled back into the catheter 118 to engage the distal stop 107. The support arms 290 are hinged inwardly and the distal collar 293 moves forward along the tubular sleeve 104. As the support arms 290 enter the catheter 118 the filter body 110 stretches as the filter body collar 115 slides along the tubular sleeve 104 proximal to the olive 120. On deployment, the catheter 118 is retracted proximally along the guidewire 101 initially bringing the collapsed filter assembly with it until it engages the proximal stop 106. The catheter sleeve then begins to release the filter freeing the support arms 290 to expand and the filter body apposes the vessel wall.

For retrieval, a retrieval catheter is introduced by sliding it over the guidewire 101 until it is positioned at the proximal end of the filter body and support frame. Pulling the guidewire 101 will initially engage the distal stop 107 with the filter element and begin to pull it into the retrieval catheter. The initial travel into the delivery catheter acts to close the proximal openings of the filter element, thus entrapping the embolic load. As the filter continues to be pulled back the filter body and the support frame are enveloped in the retrieval catheter. The collapsed filter may then be removed from the patient.

Various support frames according to the invention are described below with reference to Figs. 14 to 35. In each case the frame has a plurality of engagement segments formed on one or more support arms (some of which may be interconnected). The engagement segments are spaced-apart longitudinally and transversely when the filter is in the deployed expanded configuration to urge the

filter body into apposition with the vessel wall. The support frames of the invention provide apposition of the filter body to the wall of a vessel in which the filter is deployed. This is achieved while reducing the loading forces required to load the filter into a delivery catheter for deployment and for loading the filter into a retrieval catheter for retrieval of the filter together with any embolic material captured by the filter.

Referring to Figs. 14 to 18 there is illustrated a support frame indicated generally by the reference numeral 30 for a filter 31. The filter support frame 30 comprises a plurality of support elements each of which extend in a longitudinal direction. Some of the support elements provide support for one portion of the filter body 31 and some provide support for another portion of the filter body 31. In this case there are six support arms, three arms 30, 31, 22 providing support for a proximal end of the filter body 31 and three arms 23, 24, 25 providing support for a distal end of the filter body 31. The support arms 20, 21, 22, 23, 24, 25 each have engagement sections to engage the filter body. The engagement segments are spaced-apart longitudinally and transversely when the filter is in the deployed expanded configuration. Apposition is thereby improved while loading forces are greatly reduced allowing the filter to be more easily loaded and retrieved.

Referring to Fig. 19 there is illustrated another support frame 40 similar to that of Figs. 14 to 18. In this case adequate support is provided while omitting the distal collar 293. This frame 40 is easily formed and the same principle may be applied to other frames as those described above and below.

Referring to Fig. 20 there is illustrated another support frame 50 which comprises four support arms 51, 52, 53, 54. Each of the arms 51, 52, 53, 54 is of at least partially helical shape and different engagement segments 51a, 52a, 53a, 54a of the arms are spaced-apart longitudinally and transversely when the filter is in the deployed expanded configuration illustrated. This arrangement is especially

advantageous because it is relatively easily formed and provides excellent apposition with reduced loading forces.

Referring to Fig. 21 there is illustrated another support frame 55 according to the invention. The support frame 55 comprises six support elements 56, one of which is shown in Fig. 21(a). Each element 56 includes a distal or proximal tether section 57 and a closed loop portion 58 extending from the tether section 57. The loops 58 have engagement sections 59 and the engagement sections of the frame are longitudinally and transversely spaced-apart to achieve apposition in a central section of the frame 55.

Referring to Fig. 22 there is illustrated a further support frame 60 comprising six separate support elements 61, 62, 63, 64, 65, 66 which are again arranged to provide engagement segments 61a, 62a, 63a, 64a, 65a, 66a which are longitudinally and transversely spaced-apart to provide apposition while requiring reduced loading forces.

Referring to Fig. 23 another support frame 70 of the invention is made from twisted wires of a shaped memory/superelastic material such as nitinol. In this there are four support elements, each provided by a twisted wire 71. The wires 71 are joined together by twisting at proximal and distal ends. The wires 71 are joined together in a central region between the distal and proximal ends to form a lattice-like structure 72 which defines a plurality of longitudinally and transversely spaced-apart engagement segments.

Referring to Figs. 24 there is illustrated a support frame 75 which is in the form of a lattice-like arrangement to achieve substantial apposition to a vessel wall in use as illustrated in Fig. 25.

In Fig. 26 there is illustrated a support frame 76 similar to the frame 75 of Figs. 24 and 25. In this case the lattice in a central region is of generally hexagonal shape.

Referring to Figs. 27 there is illustrated a filter comprising a filter membrane 78 supported by a support frame 79. The support frame 79 comprises a distal lattice portion 79a, a proximal lattice portion 79b and a series of interconnecting struts in a central portion 79c. In this case the support frame 79 is attached by connections 80 to the filter membrane 78. The filter support frame 79 is mounted to the filter body and is independent of the guidewire. Therefore lateral movement of the guidewire will not affect the position of the filter support frame and apposition will not be adversely affected by guidewire movement.

Referring to Fig. 28 another support frame 82 according to the invention comprises a number of frame elements which divide intermediate the proximal and distal ends into loops 83 which define engagement segments.

In Fig. 29 there is illustrated another support frame 85 similar to the frame of Fig. 28 and like parts are assigned the same reference numerals. In this case the frame elements 82 are not interconnected at the distal end.

Referring now to Figs. 30 and 31 there is illustrated another filter support frame 85 according to the invention which is similar to the embodiment of Fig. 21 described above and like parts are assigned the same reference numerals. In this case the filter frame is proximally connected by means of two or more, preferably three flexible, (low column strength) threads/monofilaments 86. The threads 86 may be moved individually and independently of the intermediate section between a slack and taut configurations. This allows for a greater freedom of movement of the guidewire relative to the centre of the lumen without distorting the filter element. This is particularly advantageous in curved vasculatures where the guidewire may have the tendency to move away from the centre of the lumen, or in embodiments such as offset filters where the delivery of interventional catheters proximal to the filter may cause the guidewire to move towards the centre thus causing the filter to distort.

Referring to Figs. 32 and 33 there is illustrated an offset filter 90 according to the invention. The frame may be of nitinol wire of slotted tube configuration. One or more support elements 91 define a loop like structure at an angle at the proximal end to define a proximal inlet hole 92. The design for the intermediate and the distal sections of the filter may vary. In the embodiment illustrated there are two support elements 91 which form a partial helical structure along the periphery of the filter membrane. The offset design allows for a single, large proximal hole diameter, thus enabling the capture of large emboli and also maximum space for blood flow within the filter. The guidewire enters the filter through a proximal collar off the centre of the vasculature.

Referring to Figs. 34 and 35 there is illustrated another offset filter 95 according to the invention which is similar to the filter of Figs. 32 and 33. In this case there is a single support element 96. The membrane is self supported at the distal end

The support frame may comprise one or a number of support elements extending in a substantially longitudinal direction. In a preferred embodiment, at least a portion of the longitudinal support element is offset by less than 45° from its longitudinal axis. This provides circumferential apposition while greatly reducing the loading forces. In its collapsed configuration, the support elements are preferably offset within 10° preferably within 5° of the longitudinal axis.

It will be appreciated that the local stiffeners of the support element can be reduced in the collapsed state by having an undulating/curved section about which the collapsed filter can bend. This provides increased flexibility during delivery in an arrangement such as that of Fig. 20 described above.

The invention is not limited to the embodiments hereinbefore described which may be varied in both construction and detail.

Claims

CLAIMS

1. An embolic protection device comprising:

a collapsible filter element for delivery through a vascular system of a patient;

the filter element comprising a collapsible filter body and a filter support frame contacting the filter body;

the collapsible filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

the filter support frame having a longitudinal axis and being movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body in the expanded position;

the frame having a plurality of engagement segments, the engagement segments being spaced-apart longitudinally and transversely when the filter is in the deployed expanded configuration to urge the filter body into apposition with the vessel wall.

2. An embolic protection device as claimed in claim 1 wherein the engagement segments define at least one at least partially substantially helical engagement track.

3. An embolic protection device as claimed in claim 1 or 2 wherein the frame comprises a number of frame elements, at least some of the frame elements having an engagement segment.

4. An embolic protection device as claimed in claim 3 wherein at least some of the frame elements are interconnected.

5. An embolic protection device as claimed in any preceding claim wherein the frame has an intermediate section and a proximal section extending from the intermediate section, the engagement segments being provided in the intermediate section of the frame.

6. An embolic protection device as claimed in claim 5 wherein the proximal section of the frame extends radially inwardly of the intermediate section and defines at least one inlet hole to accommodate inflow of embolic material to be captured in the filter.

7. An embolic protection device as claimed in claim 6 wherein the proximal section of the frame has a proximal mounting for mounting on a filter carrier.

8. An embolic protection device as claimed in claim 7 wherein the proximal mounting is substantially tubular.

9. An embolic protection device as claimed in any of claims 5 to 8 wherein the proximal mounting is offset with respect to the longitudinal axis of the support frame.

10. An embolic protection device as claimed in any of claims 5 to 9 wherein the proximal section of the frame is flexible with respect to the intermediate section of the frame.

11. An embolic protection device as claimed in claim 10 wherein the proximal section of the frame comprises a number of proximal elements, at least some of which are of a flexible material.

12. An embolic protection device as claimed in claim 11 wherein the proximal section of the frame comprises a plurality of flexible elements of relatively low column strength which are movable individually and independently of the intermediate section between taut and slack configuration.

13. An embolic protection device as claimed in claim 11 or 12 wherein the frame includes a distal section extending from the intermediate section, the distal section of the frame being flexible with respect to the intermediate section of the frame.

14. An embolic protection device as claimed in claim 13 wherein the distal section of the frame includes a plurality of flexible elements of relatively low column strength which are movable individually and independently of the intermediate section between taut and slack configurations.

15. An embolic protection device as claimed in any of claims 12 to 14 wherein the flexible elements are thread-like elements.

16. An embolic protection device as claimed in any of claims 12 to 15 wherein at least some of the flexible elements define tethers.

17. An embolic protection device as claimed in any of claims 5 to 16 wherein the frame has a distal section extending from the intermediate section.

18. An embolic protection device as claimed in claim 17 wherein the distal section of the frame extends radially inwardly of the intermediate section.

19. An embolic protection device as claimed in claim 18 wherein the distal section of the frame has a distal mounting for mounting on a filter carrier.

20. An embolic protection device as claimed in claim 19 wherein the distal mounting is substantially tubular.

21. An embolic protection device as claimed in any of claims 17 to 20 wherein the distal mounting is offset with respect to the longitudinal axis of the support frame.

22. An embolic protection device as claimed in any of claims 17 to 21 wherein the distal section of the frame is flexible with respect to the intermediate section of the frame.

23. An embolic protection device as claimed in any of claims 5 to 21 wherein at least the intermediate section of the support frame is formed from wire.

24. An embolic protection device as claimed in any of claims 5 to 21 wherein at least the intermediate section of the support frame is formed by a slotted tube.

25. An embolic protection device as claimed in any of claims 5 to 23 wherein at least the intermediate section of the support frame is an elastic, superelastic and/or a shaped memory material.

26. An embolic protection system as claimed in any of claims 5 to 25 wherein at least the intermediate section of the support frame is of Nitinol.

27. An embolic protection device as claimed in any of claims 3 to 26 wherein the included angle defined between adjacent frame elements is less than 90°.

28. An embolic protection device as claimed in claim 27 wherein the included angle is less than 60°.

29. An embolic protection device as claimed in any of claims 3 to 28 wherein at least a portion of a support frame element is offset from the longitudinal axis by an angle of less than 45° in the expanded configuration.

30. An embolic device as claimed in any preceding claim wherein a support frame element is offset from the longitudinal axis by an angle of less than 10° when the frame is in the collapsed configuration.

31. An embolic protection device as claimed in claim 30 wherein a support frame element is offset from off the longitudinal axis by angles of less than 5° when the frame is in the collapsed configuration.

32. An embolic protection device as claimed in any preceding claim wherein the engagement segments are defined by segments of a single frame element.

33. An embolic protection device as claimed in claim 32 wherein the frame element is at least partially of helical shape.

34. An embolic protection device as claimed in any preceding claim wherein the collapsible filter body is mounted to the support frame.

35. An embolic protection device comprising:

a collapsible filter element for delivery through a vascular system of a patient;

the filter element comprising a collapsible filter body and a filter support frame contacting the filter body;

the collapsible filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

the filter support frame having a longitudinal axis and being movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body in the expanded position;

the frame having an intermediate section and a proximal section extending from the intermediate section; and

the proximal section of the frame being flexible with respect to the intermediate section of the frame.

36. An embolic protection device as claimed in claim 35 wherein the proximal section of the frame comprises a plurality of flexible elements of relatively low column strength which are movable individually and independently of the intermediate section between taut and slack configuration.

37. An embolic protection device as claimed in claim 35 or 36 wherein the frame includes a distal section extending from the intermediate section, the distal section of the frame being flexible with respect to the intermediate section of the frame.

38. An embolic protection device as claimed in claim 37 wherein the distal section of the frame includes a plurality of flexible elements of relatively low column strength which are movable individually and independently of the intermediate section between taut and slack configurations.

39. An embolic protection device as claimed in any of claims 36 to 38 wherein the flexible elements are thread-like elements.

40. An embolic protection device as claimed in any of claims 36 to 39 wherein at least some of the flexible elements define tethers.

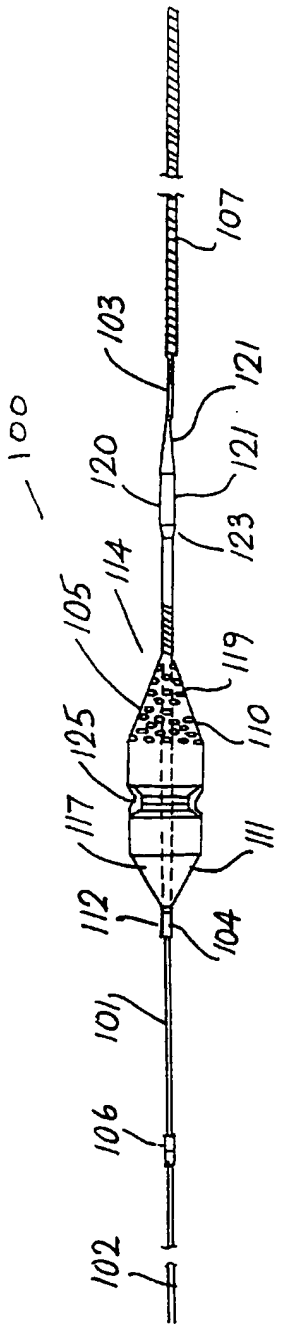
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Fig. 1

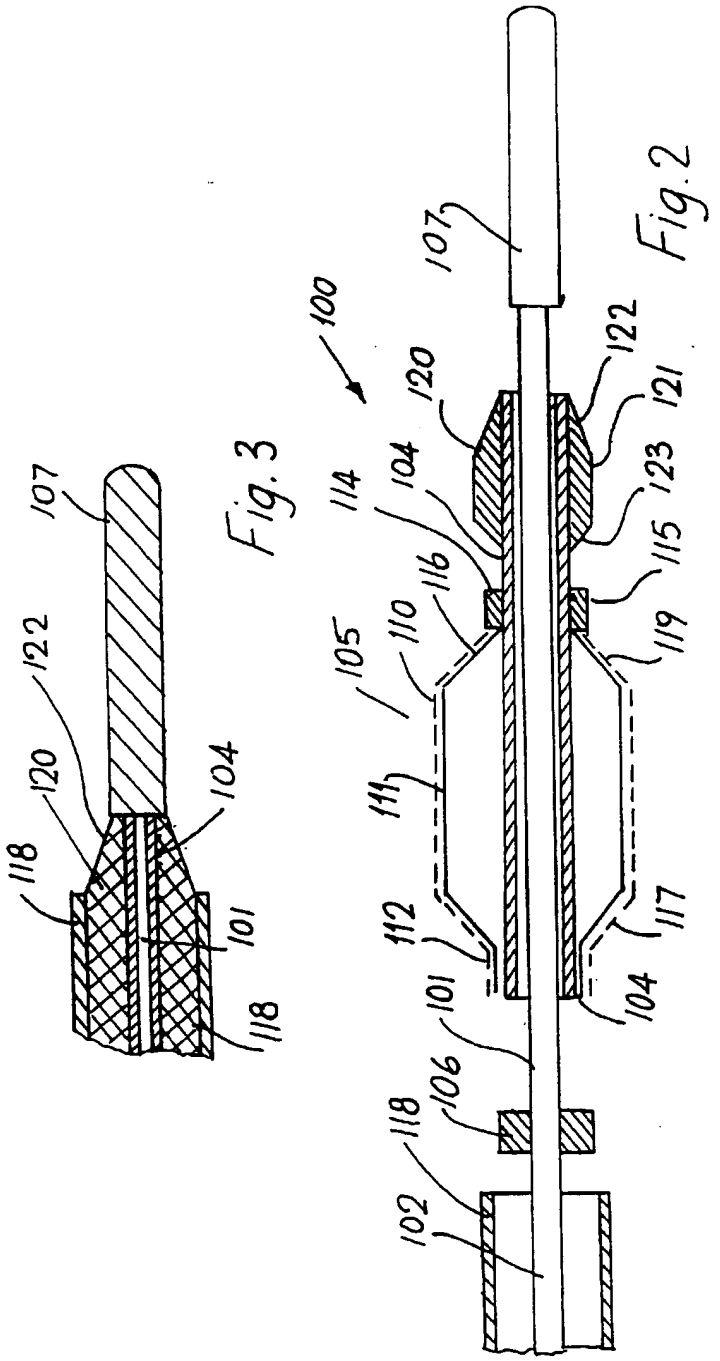
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Fig. 2

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Fig. 3

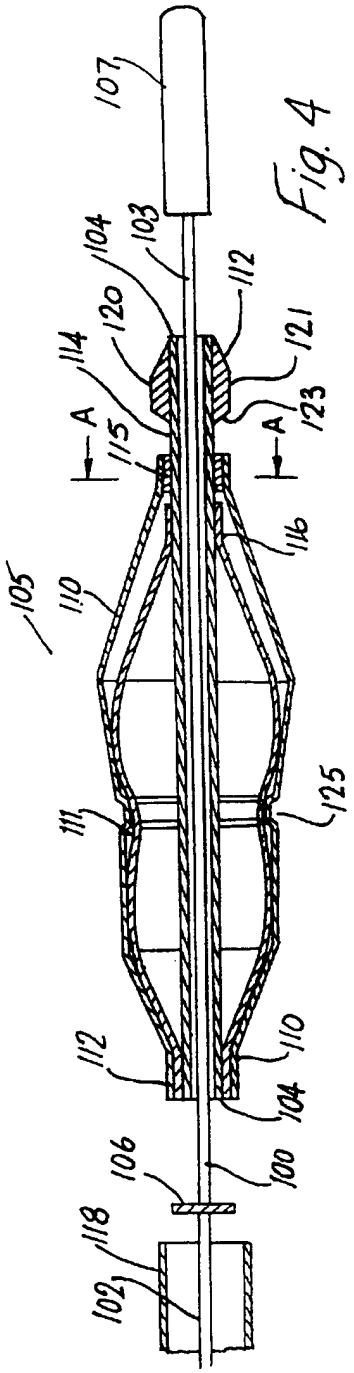

Fig. 4

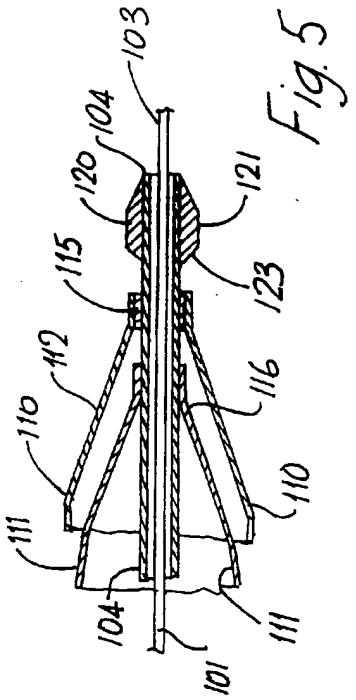

Fig. 5

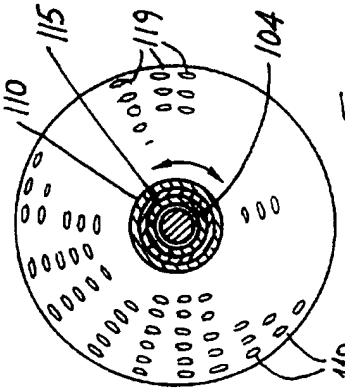

Fig. 6

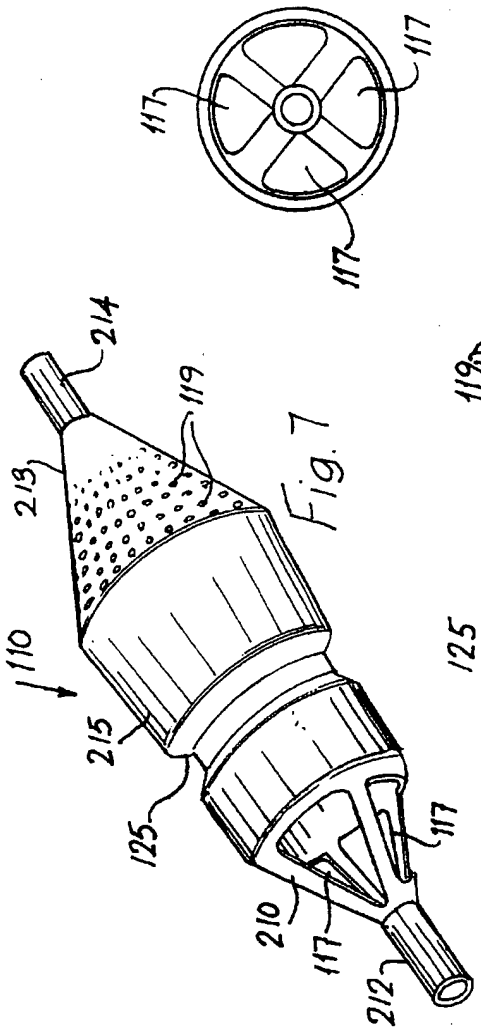
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Fig. 7

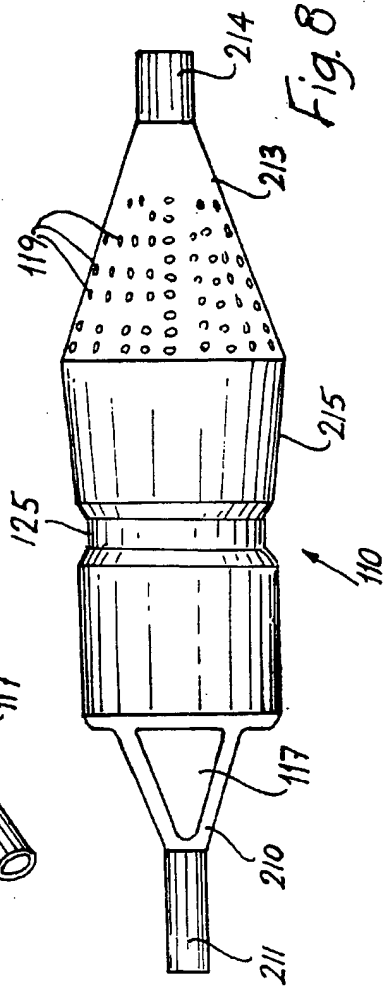
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Fig. 8

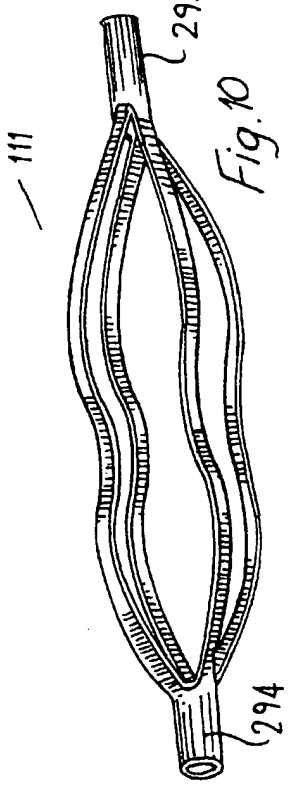


Fig. 10

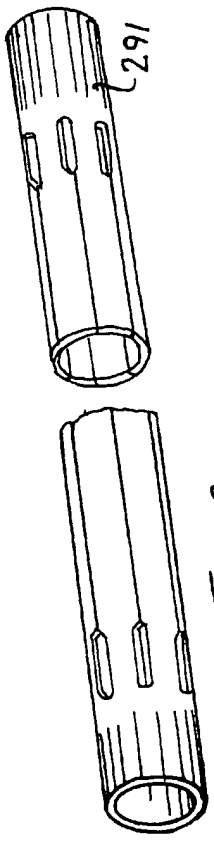


Fig. 12

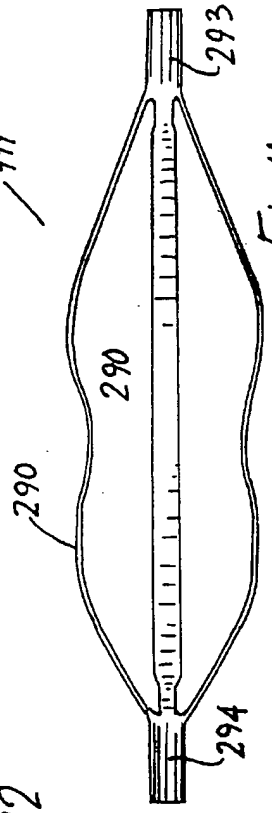


Fig. 11

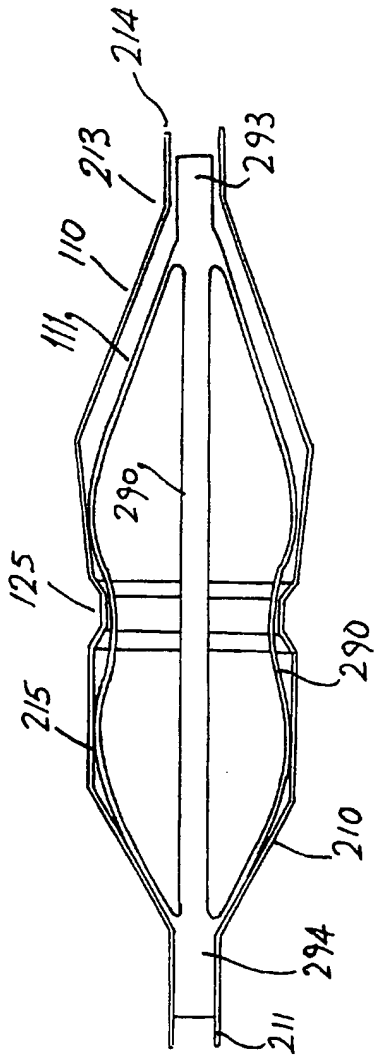


Fig. 13

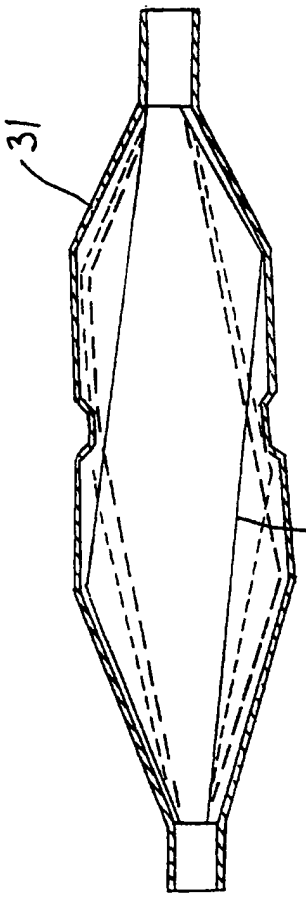


Fig. 14

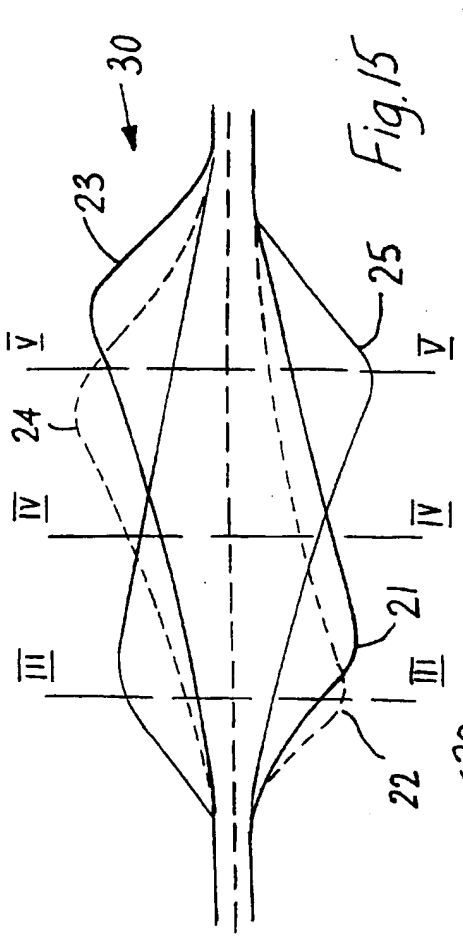


Fig. 15

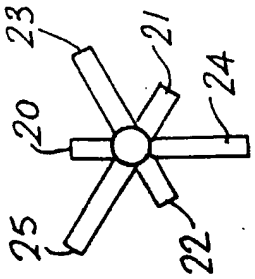


Fig. 18

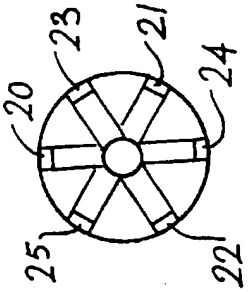


Fig. 17

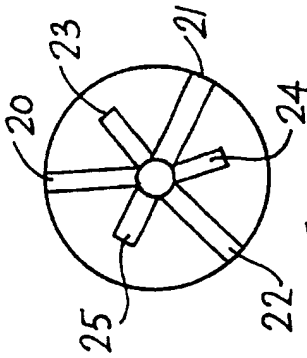


Fig. 16

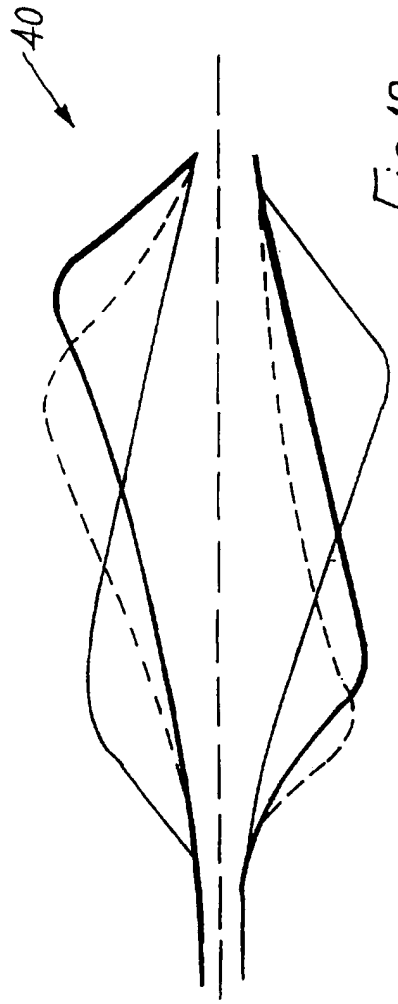


Fig. 19

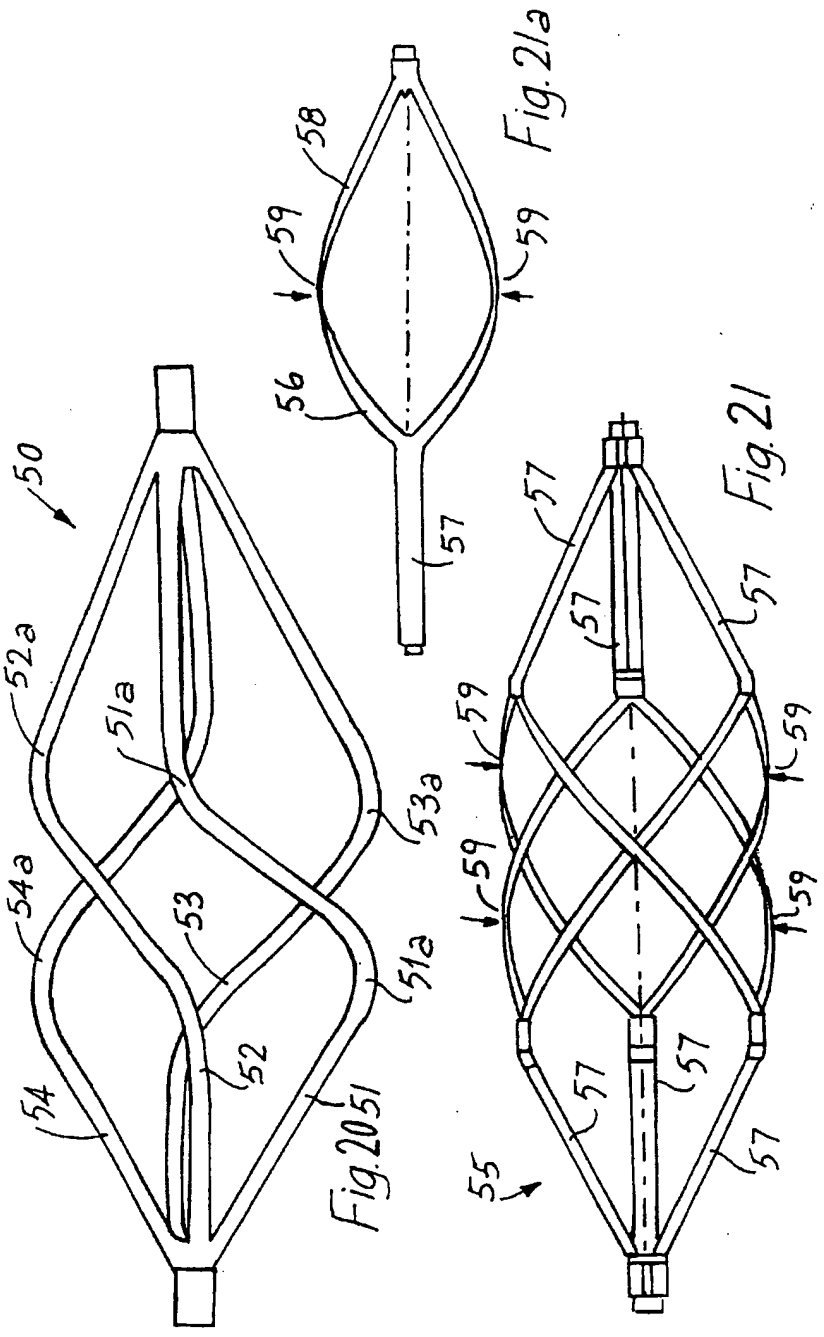


Fig. 21a

Fig. 2051

Fig. 21

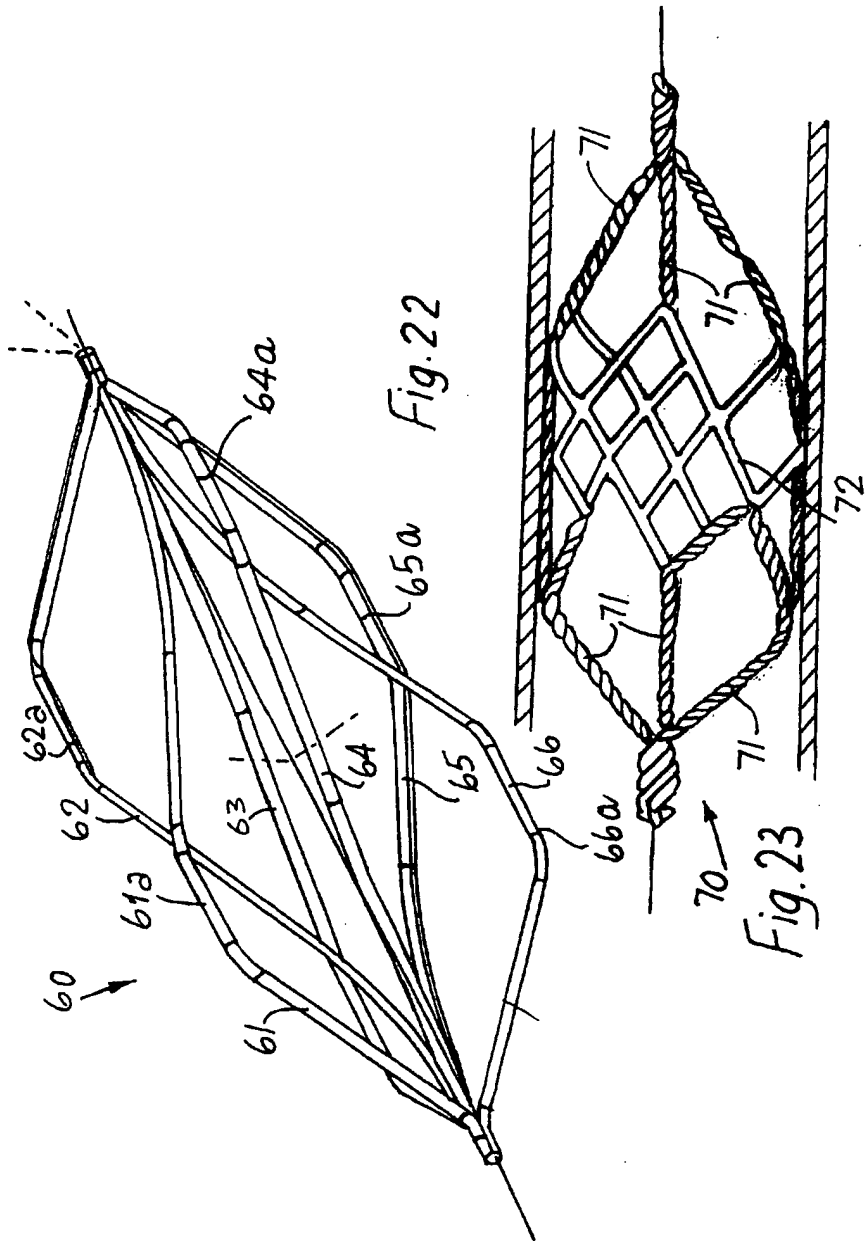


Fig.22

Fig.23

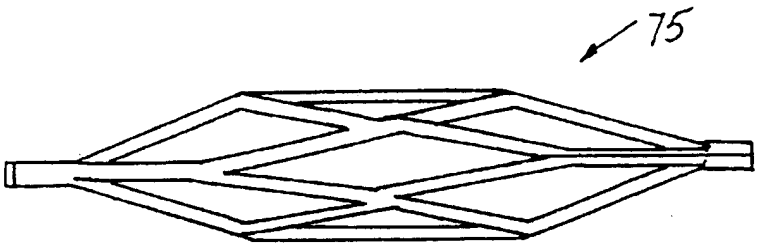


Fig. 24

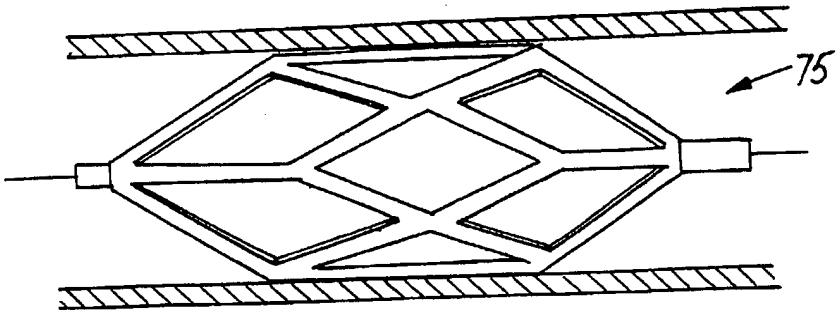


Fig. 25

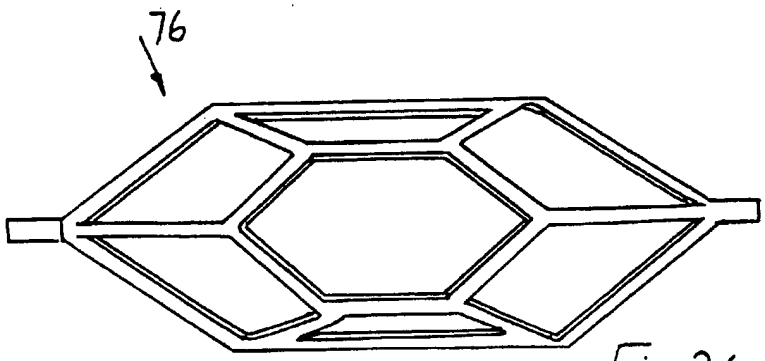


Fig. 26

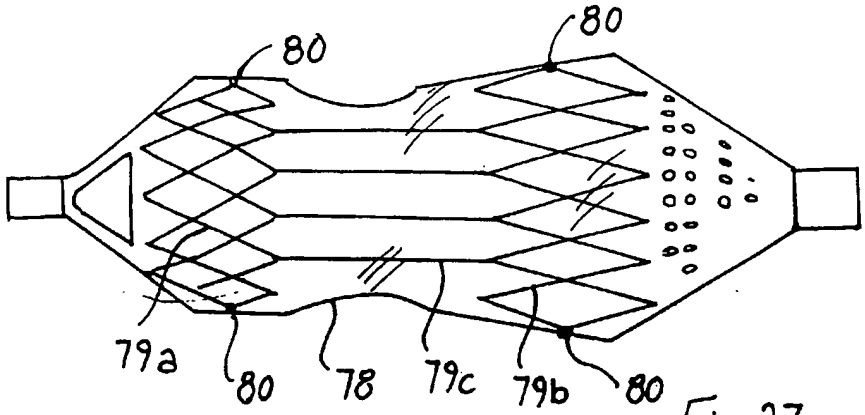


Fig. 27

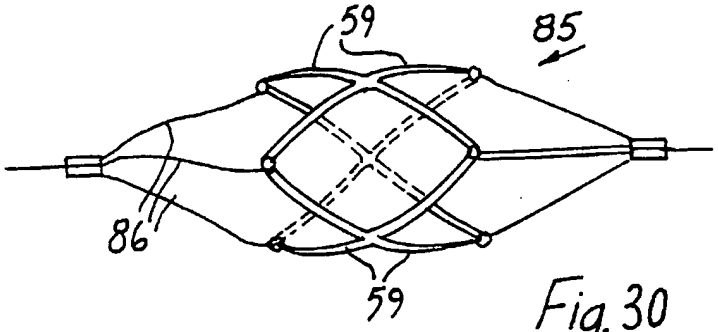
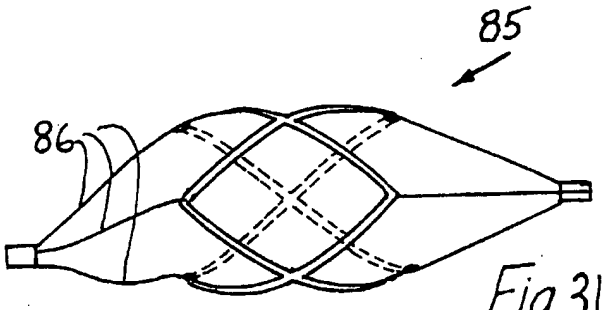


Fig. 30



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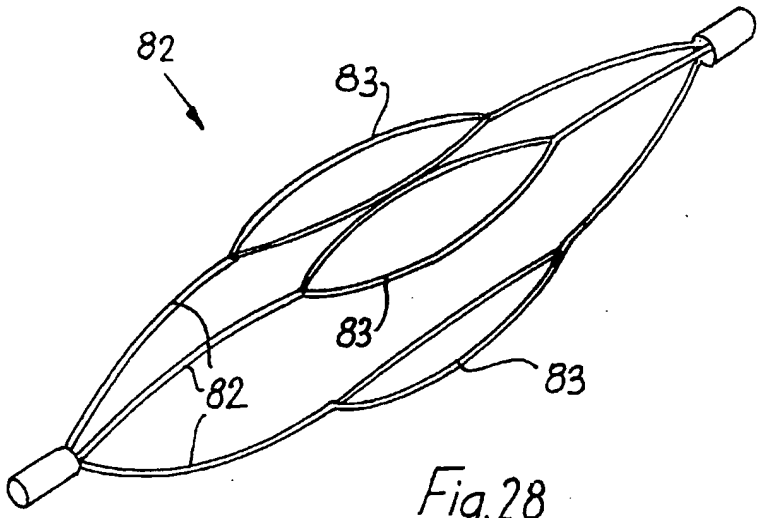

Fig. 28

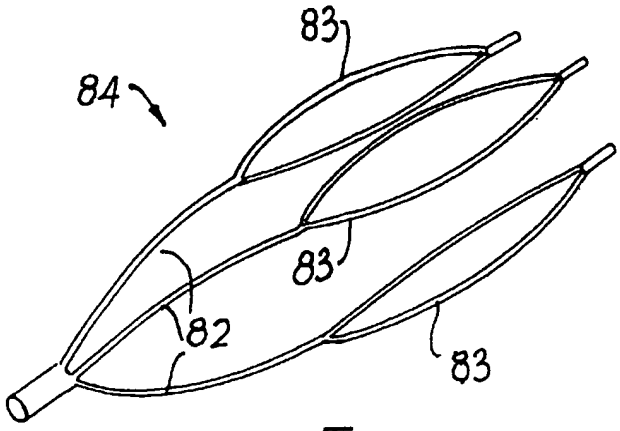

Fig. 29

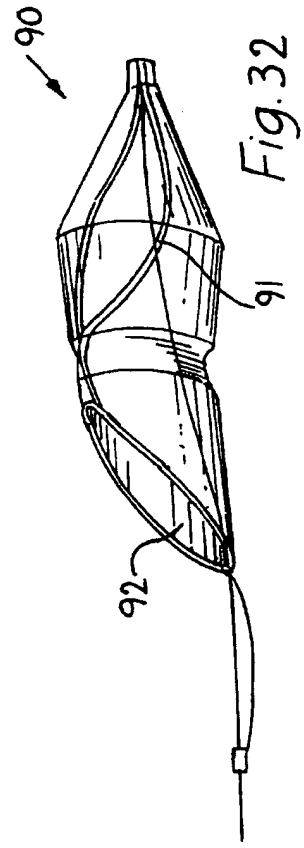

Fig. 32

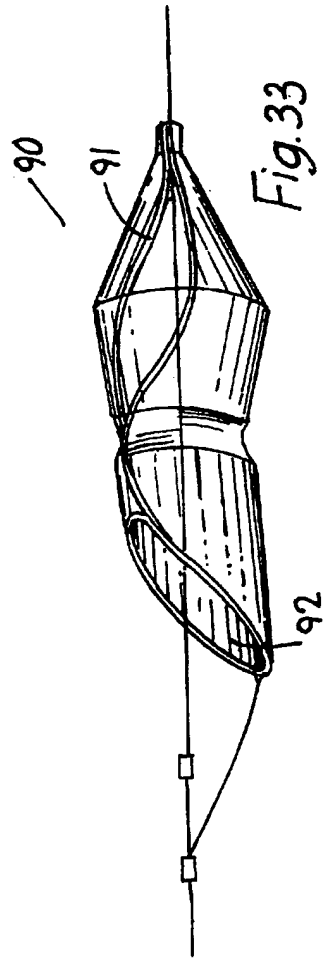

Fig. 33

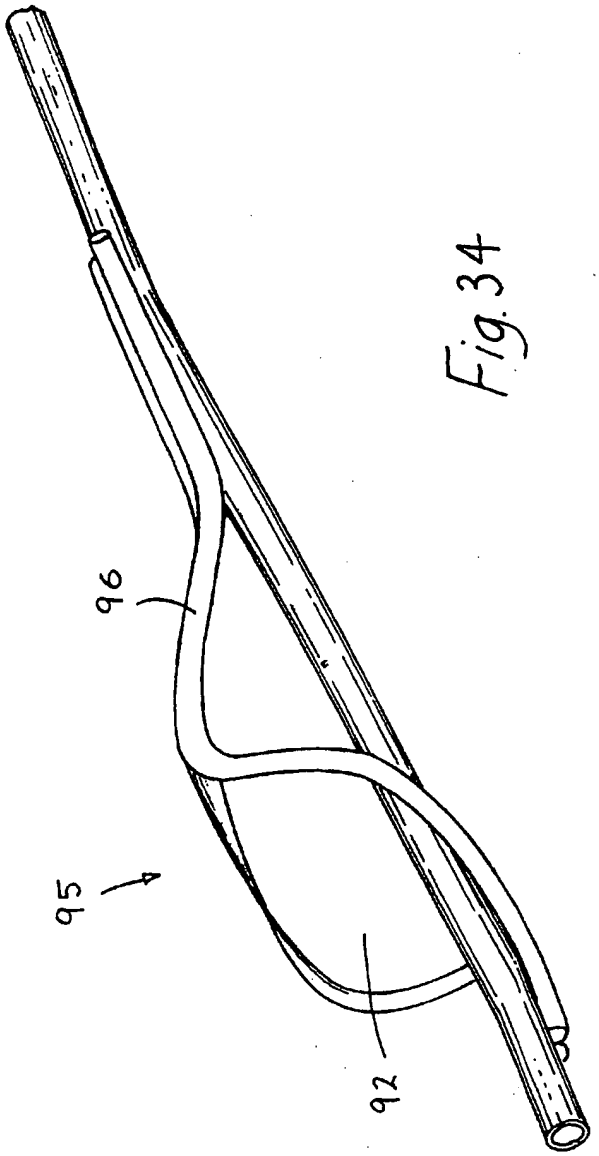

Fig. 34

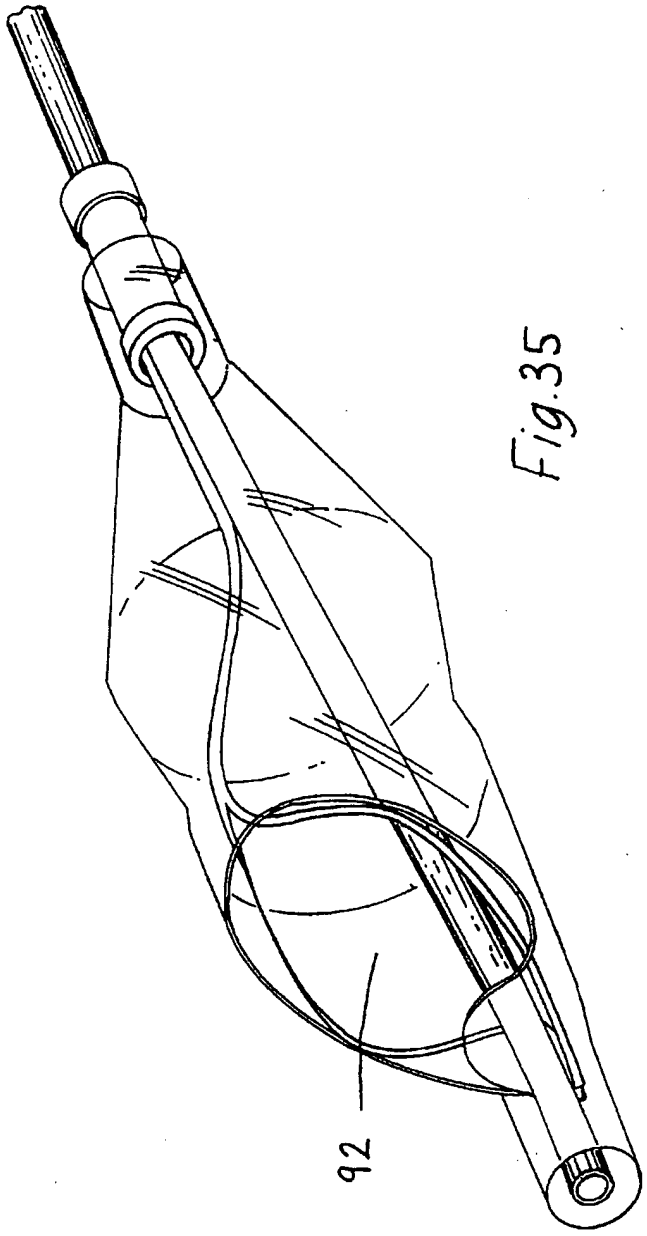

Fig.35

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 00/00054

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 16382 A (CARDEON CORPORATION) 8 April 1999 (1999-04-08) abstract; figures	1,35
A	WO 98 39053 A (SCIMED LIFE SYSTEMS, INC.) 11 September 1998 (1998-09-11) abstract; figures	1,35

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 August 2000	16/08/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IE 00/00054

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